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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,244	SAREEN ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-127* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-127* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9, drawn to a method for identifying an inhibitor of cysteine: glucosaminyl inositol ligase. **Election of this group requires further election of one glucosaminyl inositol or one derivative thereof from claims 4, 5 and 7; as well as one candidate compound type from claim 9, as explained below.**

Group II, claim 10, drawn to an inhibitor of cysteine: glucosaminyl inositol ligase. **Since claim 10 depends from claim 1, election of this group requires further election of one glucosaminyl inositol or one derivative thereof from claims 4, 5 and 7; as well as one candidate compound type from claim 9, as explained below.**

Group III, claims 11-19, drawn to a method for decreasing virulence of a pathogenic cysteine: glucosaminyl inositol ligase-producing bacterium in mammalian cells. **Election of this group requires further election of one amino acid sequence from claims 12, 16 and 17, as explained below.**

Group IV, claims 20-28, drawn to a method for increasing sensitivity of a pathogenic cysteine: glucosaminyl inositol ligase-producing bacterium in mammalian cells to an antibiotic. **Election of this group requires further election of one amino acid sequence from claims 23, 25 and 26, as explained below.**

Group V, claims 29-33, drawn to a method for inhibiting the growth of Cys-GlcN-Ins-producing bacterium in a mammal. **Election of this group requires further election of one amino acid sequence from claim 33, as explained below.**

Group VI, claims 34 and 35, drawn to an inhibitor of cysteine: glucosaminyl inositol ligase, wherein the moiety replacing the carboxyl group is CH2OPO(OH)OR.

Group VII, claims 34 and 36, drawn to an inhibitor of cysteine: glucosaminyl inositol ligase, wherein the moiety replacing the carboxyl group is CONHSO2OR.

Group VIII, claims 37-41, drawn to a method for identifying an inhibitor of acetyl-CoA: cysteinyl glucosaminyl inositol acetyltransferase. **Election of this group requires further election of one amino acid sequence from claim 38; as well as one candidate compound from claim 41, as explained below.**

Group IX, claim 42, drawn to an inhibitor of acetyl-CoA: cysteinyl glucosaminyl inositol acetyltransferase. **Since claim 42 depends from claim 37, election of this group requires further election of one amino acid sequence from claim 38; as well as one candidate compound from claim 41, as explained below.**

Group X, claims 43-51, drawn to a method for decreasing the virulence of a pathogenic acetyl-CoA: cysteinyl glucosaminyl inositol acetyltransferase-producing bacterium in mammalian cells. **Election of this group requires further election of one amino acid sequence from claims 44, 48 and 49, as explained below.**

Group XI, claims 52-60, drawn to a method for increasing sensitivity of a pathogenic acetyl-CoA: cysteinyl glucosaminyl inositol acetyltransferase-producing bacterium in mammalian cells to an antibiotic. **Election of this group requires further election of one amino acid sequence from claims 55, 57 and 58, as explained below.**

Group XII, claims 61-65, drawn to a method for inhibiting growth of an acetyl-CoA: cysteinyl glucosaminyl inositol acetyltransferase-producing bacterium in a mammal. **Election of this group requires further election of one amino acid sequence from claim 65, as explained below.**

Group XIII, claims 66-69, drawn to a method for identifying an inhibitor of MshA glycosyltransferase. **Election of this group requires further election of one amino acid sequence from claim 67; as well as one candidate compound from claim 69, as explained below.**

Group XIV, claim 70, drawn to an inhibitor of MshA glycosyltransferase. **Since claim 70 depends form claim 66, election of this group requires further election of one amino acid sequence from claim 67; as well as one candidate compound from claim 69, as explained below.**

Group XV, claims 71-79, drawn to a method for decreasing the virulence of a pathogenic MshA glycosyltransferase-producing bacterium in mammalian cells. **Election of this group requires further election of one amino acid sequence from claims 72, 76 and 77, as explained below.**

Group XVI, claims 80-88, drawn to a method for increasing sensitivity of a pathogenic MshA glycosyltransferase-producing bacterium in mammalian cells to an antibiotic.

Election of this group requires further election of one amino acid sequence from claims 83, 85 and 86, as explained below.

Group XVII, claims 89-93, drawn to a method for inhibiting growth of a GlcNAc-Ins-producing bacterium in a mammal. **Election of this group requires further election of one amino acid sequence from claim 93, as explained below.**

Group XVIII, claims 94-97, drawn to a method for identifying an inhibitor of mycothiol biosynthesis, wherein the inhibition is by inhibition of cysteine: glucosaminyl inositol ligase. **Election of this group requires further election of MshC, MshD or MshA from claim 94; as well as one candidate compound from claim 96, as explained below.**

Group XIX, claims 94-96 and 98, drawn to a method for identifying an inhibitor of mycothiol biosynthesis, wherein the inhibition is by inhibition of acetyl-CoA: Cys-GlcN-Ins acetyltransferase. **Election of this group requires further election of MshC, MshD or MshA from claim 94; as well as one candidate compound from claim 96, as explained below.**

Group XX, claims 94-96 and 99, drawn to a method for identifying an inhibitor of mycothiol biosynthesis, wherein the inhibition is by inhibition of MshA glycosyltransferase. **Election of this group requires further election of MshC, MshD or MshA from claim 94; as well as one candidate compound from claim 96, as explained below.**

Group XXI, claim 100, drawn to an inhibitor of mycothiol biosynthesis. **Since claim 100 depends from claim 94, election of this group requires further election of MshC, MshD or MshA from claim 94; as well as one candidate compound from claim 96; as well as one method step from claims 97-99, as explained below.**

Group XXII, claims 101, 102 and 105-108, drawn to a method for increasing sensitivity of a pathogenic mycothiol-producing bacterium in mammalian cells to an antibiotic, wherein the inhibitor inhibits cysteine: glucosaminyl inositol ligase activity. **Election of this group requires further election of MshC, MshD or MshA from claim 101; as well as one sequence from claims 106 and 107, as explained below.**

Group XXIII, claims 101, 103 and 105-108, drawn to a method for increasing sensitivity of a pathogenic mycothiol-producing bacterium in mammalian cells to an antibiotic, wherein the inhibitor inhibits acetyl-CoA: Cys-GlcN-Ins acetyltransferase activity. **Election of this group requires further election of MshC, MshD or MshA from claim 101; as well as one sequence from claims 106 and 107, as explained below.**

Group XXIV, claims 101 and 104-108, drawn to a method for increasing sensitivity of a pathogenic mycothiol-producing bacterium in mammalian cells to an antibiotic, wherein

the inhibitor inhibits MshA glycosyltransferase activity. **Election of this group requires further election of MshC, MshD or MshA from claim 101; as well as one sequence from claims 106 and 107, as explained below.**

Group XXV, claims 101 and 105-109, drawn to a method for increasing sensitivity of a pathogenic mycothiol-producing bacterium in mammalian cells to an antibiotic, wherein the inhibitor inhibits intracellular production of mycothiol. **Election of this group requires further election of MshC, MshD or MshA from claim 101; as well as one sequence from claims 106 and 107, as explained below.**

Group XXVI, claims 110-113, drawn to a live mutant actinomycete. **Election of this group requires further election of one gene from claim 110, as explained below.**

Group XXVII, claims 114-117, drawn to a purified cysteine: glucosaminyl inositol ligase.

Group XXVIII, claims 118-121, drawn to a purified acetyl-CoA: Cys-GlcN-Ins acetyltransferase.

Group XXIX, claims 122-124, drawn to a purified MshA glycosyltransferase.

Group XXX, claim 125, drawn to an expression vector comprising SEQ ID NO: 49.

Group XXXI, claim 125, drawn to an expression vector comprising SEQ ID NO: 1.

Group XXXII, claim 125, drawn to an expression vector comprising SEQ ID NO: 48.

Group XXXIII, claims 126 and 127, drawn to a method for identifying an inhibitor of cystein: glucosaminyl inositol ligase comprising the steps of claims 126 and 127.

The inventions listed as Groups I-XXXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claims are directed to methods or compounds, wherein the claims recite a multitude of amino acid and polynucleotide sequences. According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the

alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed sequences, the Markush group shall be regarded as being of similar nature when

> (A) all alternatives have a common property or activity and; (B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives; or (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art-recognized class of compounds in the art to which the invention pertains.

The instant sequences are considered to be each separate inventions for the following reasons: The sequences do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. The sequences each behave in a different way in the context of the claimed invention. Each member of the class cannot be substituted, one for the other, with the expectation that the same intended result would be achieved. Further, the sequences do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the sequences is lacking and each sequence claimed is considered to constitute a special technical feature.

Furthermore, claims 9, 41, 69 and 96 recite that the candidate compound is a polypeptide, polynucleotide or small molecule. Each of the candidate compounds do not have a common property or activity, do not share a common structure and do not represent one art-recognized class of compounds. Accordingly, unity of invention

between the candidate compounds is lacking and each candidate compound claimed is considered to constitute a special technical feature.

Furthermore, claims 94 and 101 recite that the enzyme is MshC, MshD or MshA. Claim 110 recites that the gene is mshC, mshD or mshA. Each of the enzymes and genes do not have a common property or activity, do not share a common structure and do not represent one art-recognized class of compounds. Accordingly, unity of invention between the enzymes, as well as between the genes, is lacking and each enzyme or gene claimed is considered to constitute a special technical feature.

Accordingly, upon election of a group, applicant is further required to elect one sequence and/or one candidate compound and/or one gene and/or one enzyme, as specified in the groups listed above.

Furthermore, 37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn **only** to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In the instant case, the product is not the first claimed invention and therefore there is no unity of invention between the products and processes. Furthermore, the instant claims do not all fall into one of the only 5 combinations of categories which can have unity of invention as defined by 1.475(b). The claims are directed to multiple processes comprising separate and distinct steps, as well as to separate and distinct products that are structurally distinct. The claims are directed to inhibitors with completely different structural characteristics based on different sequences, as well as to methods with completely different steps. Therefore, there is no special technical feature linking the groups listed above.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of claims 4, 5 and 7 are as follows:

D-glucosamine, a fluorescent derivative of glucosaminyl inositol, and 1D-myo-inosityl 2-amino-2-deoxy-α-D-glucopyranoside.

Upon election of group I, applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the derivatives are structurally distinct, each requiring a separate search and corresponding examination. The derivatives do not contain a common structural core.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755. The examiner can normally be reached on Monday-Thursday 6:30 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy H. Bowman/
Patent Examiner
Art Unit 1635